REMARKS

This Amendment & Response is submitted together with a Request for Continued Examination (RCE) in response to the final Office Action dated December 15, 2008. A three-month extension of time is also filed herewith. Therefore, the time period for response extends up to and includes June 15, 2009.

In the present Amendment and Response, claims 1 and 2 are amended, with support for these amendments found in the specification at least at page 5, line 19 through page 8, line 1. Claim 7 has been amended to correct a typographical error. Claims 4, 9, and 11-14 are canceled in this response without prejudice or disclaimer. Claims 1-3 and 7 remain pending. No new matter is added. Reconsideration and allowance of the present application is respectfully requested in view of the above amendments and following remarks.

Restriction

The Office Action required restriction to a single invention in the Office Action, finding that the previously presented claims were directed toward a process and an apparatus for its practice. The groups were described in the Office Action as follows:

I. Claims 1, 4, 7, 9, and 11, drawn to a method of determining the cardiac output of a patient.

II. Claims 12-14, drawn to an apparatus for measuring the diameter of the pulmonary valve of a patient.

In response to the Restriction Requirement, Applicant elects Group I (claims 1-4, 7, 9, and 11), without traverse. As noted above, Applicant has canceled claims 4, 9, and 12-14 in the present response. Thus, elected claims 1-3 and 7 remain pending.

Rejections Under 35 U.S.C. § 103

A. Claims 1-3, 7, and 11

At paragraph 6 of the subject Action, claims 1-3, 7, and 11 were rejected under §103(a) as being unpatentable over Nidorf et al. (J Am Coll Cardiol 1992; 19:983-8). Applicant respectfully traverses the rejection, and does not acquiesce to the characterization of the claims and/or reference as set forth in the Office Action.

Claim 1 recites a method of determining the cardiac output of a patient, and is amended in the present response to clarify how the cardiac output is determined. Claim 1 now requires, among other elements, "calculating, using a single variable formula, the diameter of the pulmonary valve of the patient wherein the single variable is the patient's height, and thereby calculating the cross sectional area of the pulmonary valve." The claim also requires "calculating a value for the cardiac output of the patient as the product of the heart rate, the velocity time integral and the cross sectional area of the heart valve."

1. Allowability of Claim 1 Over Nidorf et al.

First, claim 1 is not rendered obvious by Nidorf et al. at least because Nidorf et al. fails to disclose and/or teach the particular method claimed. Specifically, Nidorf et al. fails to disclose and/or suggest calculation of a diameter or a cross-sectional area of the pulmonary valve as claimed. Nidorf et al. describes equations for calculation of the diameter of the aortic valve, and hence its cross-sectional area (CSA). Nidorf et al. is explicit in the cardiological dimensions examined, i.e. the end-diastolic diameter of the aortic annulus, the end systolic (maximal) diameter of the left atrium, the maximal diastolic diameter of the left ventricle and the diastolic length of the left ventricular cavity. None of these measurements correspond to measurement of a patient's height to determine cross sectional area of a pulmonary valve. In contrast to Nidorf et al., the claimed method for determining the cardiac output of a patient may be used with patients with whom, as a result of trauma for example, echocardiographic determination of the aortic velocity-time integral (e.g., Nidorf et al.) is not possible.

The Examiner asserts that "it would be obvious to follow the method of Nidorf et al. to find and use a single variable formula . . . to calculate the diameter of the pulmonary valve of a patient wherein the single variable is the patient's height." Applicant respectfully disagrees with this assertion. No reference is made in Nidorf et al. to a study of the pulmonary valve or annulus and, although that reference states "height is the strongest predictor of cardiac chamber dimensions" (see Nidorf et al. at page 988, col. 2), no indication is given that this statement extends beyond those dimensions specifically investigated (i.e., the end-diastolic diameter of the aortic annulus, the end systolic diameter of the left atrium, the maximal diastolic diameter of the left ventricle and the diastolic length of the left ventricular cavity). No rationale is given in Nidorf et al. as to why it might be safe to extend the results of the study to other cardiac feature

dimensions. Moreover, Nidorf et al. indicates that the indexing of cardiac dimensions needs to be "accurate" (see page 985, col. 2), which suggests against the estimation methodology claimed.

Therefore, the method of determining cardiac output recited in claim 1 is not rendered obvious by Nidorf et al.

2. Allowability of Claim 1 Over Nidorf et al. and Phillips

Second, Applicant notes that claim 1 in its present form is allowable over the combination of references applied against the claims in the Office Action, i.e. Nidorf et al. and Phillips (U.S. Patent No. 6,565,513).[1] This is because Philips does not overcome the deficiencies of Nidorf et al. regarding calculation of a diameter or a cross-sectional area of the pulmonary valve.

As previously described, Nidorf et al. fails to disclose and/or suggest calculation of a diameter or a cross-sectional area of the pulmonary valve. Phillips also fails to disclose and/or suggest such an element. Rather, Phillips relates to use of ultrasound to monitor cardiac output. Phillips is silent with respect to patient height or its use in a single-variable calculation to determine the diameter of the pulmonary valve.

Therefore, claim 1 is allowable over not only Nidorf et al. standing alone, but over the combination of Nidorf et al. and Phillips as well.

3. Response to Examiner's Comments

In response to Applicant's previous arguments regarding the difficulty of measuring the diameter of the pulmonary valve, the Examiner notes that "Phillips . . . appears to have no difficulty in obtaining the pulmonary artery diameter." Office Action at paragraph 8. Applicant respectfully disagrees with this characterization, and notes that Phillips makes no reference to the ease (or otherwise) with which the pulmonary valve diameter may be obtained.

The Examiner further asserts that "it would have been obvious to one of ordinary skill in the art to obtain the pulmonary annular [diameter] using the method taught by Nidorf et al." Office Action at paragraph 7. However, in view of the difficulty in obtaining the pulmonary diameter discussed above, Applicant respectfully traverses this assertion. Further, Applicant

[1] Although the present Office Action rejects claim 1 based on Nidorf et al. alone, Applicant addresses the combination of Nidorf et al. and Phillips in an effort to expedite allowance of claim 1.

believes that this point is moot -- since the claimed method obtains the pulmonary annular diameter differently from that disclosed and/or taught by Nidorf et al. In contrast to Nidorf et al., Applicant recognizes that, in the absence of significant regurgitation or trans-septal flow, aortic and pulmonary cardiac output must be equal. Applicant further recognizes that this fact provides an opportunity to estimate the diameter of the pulmonary annulus, as recited in claim 1. Such a solution provides a comparatively more accessible technique than direct measurement by echocardiographic techniques (e.g., by Nidorf et al.).

Applicant notes that the claimed method for determining the cardiac output of a patient provides advantages over the prior art. For example, the method may be used with patients where due to trauma an echocardiographic determination of the aortic velocity-time integral (e.g., as in Nidorf et al.) is not possible. Further, Applicant notes that the claimed determination of a linear relationship between pulmonary valve diameter and height may be used in mathematical combination with the relationship between aortic valve diameter and height from Nidorf et al. to determine an expected pulmonary valve diameter in situations in which the natural height of a patient may not readily be determined.

4. Summary, Rejection of Remaining Claims

In view of the foregoing, Nidorf et al. (alone or in combination with Phillips) does not disclose or suggest the method recited in claim 1. Claims 2-3 and 7 depend from claim 1, and so include the elements of that claim. Claim 11 is canceled in the present response, rendering rejection of that claim moot. Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of those claims as well.

Applicant does not otherwise concede the correctness of the rejection and reserves the right to make additional arguments as may be necessary.

B. Claims 4 and 9

At paragraph 7, claims 4 and 9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Phillips in view of Nidorf et al. Applicant respectfully traverses this rejection. However, in order to expedite prosecution, claims 4 and 9 are canceled in the present response, rendering the rejection of these claims moot. Applicant therefore respectfully requests reconsideration and withdrawal of the rejection of these claims.

Conclusion

In view of this Amendment and Response, Applicant respectfully requests a Notice of Allowance. There may be additional reasons that the pending subject matter is patentably distinct from the cited references in addition to those discussed herein. Applicant reserves the right to raise any such arguments in the future. If the Examiner believes that a telephone conference would advance the prosecution of the application, the Examiner is invited to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

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